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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,863	07/06/2000	David Gustafsson	3525-86	4411

23117 7590 08/10/2004
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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,863

Applicant(s)

GUSTAFSSON, DAVID

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-43 is/are allowed.
- 6) ☒ Claim(s) 20,22,23,29 and 31-35 is/are rejected.
- 7) ☒ Claim(s) 21,24-28,30,36-40 and 44-57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
- 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
- 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 20-57 are pending.

Applicants' amendment filed on May 26, 2004 is acknowledged, and applicants' response has been fully considered. Claims 20-22, 29-31, 33, 45 and 50 have been amended. Thus, claims 20-57 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 20-30, 45 and 50, under 35 U.S.C. § 112, second paragraph, is withdrawn in view of applicants' amendment to the claims and applicants' response at pages 10-11 in the amendment filed May 26, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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3. Claims 20, 22, 23, 29 and 31-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Lam *et al.* (U.S. Patent 6,602,871 B2, priority date December 23, 1998).

Lam *et al.* teach nitrogen-containing aromatic heterocycles with ortho-substituted groups such as compounds of formula (I) are useful as factor Xa inhibitors or thrombin inhibitors or pharmaceutical acceptable salts or prodrug thereof, and pharmaceutical compositions comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of at least one of the compounds or a pharmaceutical acceptable salt or prodrug thereof (column 1, lines 39-56; columns 2-8; column 31, lines 29-45; column 47, line 9-column 48, line 57), and these compounds can be administered alone or in combination with one or more additional therapeutic agents such as thrombin inhibitors or pharmaceutical acceptable salts or prodrugs thereof (column 48, line 58-column 49, line 62). The compound of formula (I) and one or more therapeutic agents such as thrombin inhibitors (i.e., boroarginine derivatives, boro peptides and argatroban, which are known low molecular weight thrombin inhibitors) or pharmaceutical acceptable salts or prodrugs thereof are administered with a pharmaceutical carrier in pharmaceutical compositions at the same time or sequentially in any order at different time points to provide the desired therapeutic effect for treating thromboembolic disorders such as deep vein thrombosis (column 49, lines 4-62; column 47, lines 9-22; column 50, line 41-column 54, line 4; claims 20, 22, 23, 29, 31-35).

In response, applicants indicate Lam *et al.* disclose specific thrombin inhibitors in addition to (separately) prodrugs of those thrombin inhibitors, there is no disclosure to use those two components in combination, as is required by the present claims; and at column 48, lines 58-63 of Lam, it is suggested that the compounds (i.e., the thrombin

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inhibitors or prodrugs thereof) may be administered alone or in combination with one or more additional therapeutic agents, such as anti-coagulant agents and, in particular, other thrombin inhibitors, however, this, at best, is a very general teaching of a combination of a prodrug of the thrombin inhibitors disclosed in Lam along with another thrombin inhibitor (not necessarily a low molecular weight thrombin inhibitor, as defined in the present application as indicate at page 9, line 5 to page 10, line 12 of the specification; pages 11-12 of the response). The response has been considered, however, the argument is not found persuasive because Lam *et al.* indicate the compounds of formula (I) (i.e., the thrombin inhibitors or prodrugs thereof) can be administered alone or in combination with one or more additional therapeutic agents, such as anti-coagulant agents and, in particular, other thrombin inhibitors (column 48, lines 58-63), and further describes several known low molecular weight thrombin inhibitors such as boroarginine derivatives, boroptides and argatroban can be used in the treatment. Therefore, the instant claims are anticipated by the reference.

Regarding the priority document (Provisional Application No. 60/113,627) of Lam's 871 patent, which has disclosed the use of the claimed compounds in combination with other thrombin inhibitors, thus the priority date (December 23, 1998) of Lam's 871 patent is valid.

4. Claims 21, 24-28, 30, 36-40 and 44-57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

5. Claims 20, 22, 23, 29 and 31-35 are rejected, and claims 21, 24-28, 30, 36-40 and 44-57 are objected to. It appears claims 41-43 are free of art and allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

CMK
July 30, 2004

Jon P. Weber
Supervising

Jon P. Weber, Ph.D.
Primary Examiner